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METHOD AND APPARATUS FOR DELIVERING CEMENT TO BONES AND/OR POSITIONING COMPONENTS

This invention relates to cement delivery and, more particularly, to a method and apparatus for delivering cement and the like to bones in the human and animal body. It also relates to positioning components to be cemented in place.

It is a well known to cement various types of prostheses or components to or in bones in the human and animal body. Likewise, treatment of bones that have been broken or are diseased may involve cementing bone together or filling a cavity in the bone. This invention is particularly applicable to the delivery of cement or the like to cavities or bores in bones (whether natural or artificial) and to the fixation of prostheses or components in such cavities or bores where desirable.

Problems with conventional techniques for cement delivery can be understood by considering the replacement of worn out, damaged or diseased joints in human and animal bodies with artificial joint prostheses. Such prostheses may comprise, for example, a replacement joint articulation, such as a metal ball and socket or other pivotal connection. Alternatively, the joint prosthesis may replace only part of the joint. For example, the ball of a ball and socket joint may be replaced with a joint prosthesis comprising an artificial replacement ball designed to sit in the original socket of a natural joint or the socket of a ball and socket joint may be replaced with a joint prosthesis comprising an artificial socket designed to fit the original ball.

Regardless of whether the joint prosthesis replaces all or part of a joint, the joint prosthesis or parts of the joint prosthesis, need to be anchored in or located

on bone adjacent or near to the joint. Joint prostheses therefore generally further comprise means for anchoring the replacement articulation, joint surface or joint part in a bone. For example, a joint prosthesis for replacing a ball and socket joint, such as the human shoulder or hip, often has a replacement articulation comprising a ball and socket. The replacement ball may be located on, or formed integrally with, anchoring means comprising a pin arranged to be inserted in the medullary canal of a bone, such as the femur or humerus, after the natural ball has been removed. Similarly, a replacement socket may be carried in anchoring means comprising a cup which is arranged to fit in the bone surrounding the socket, such as the acetabulum or scapula, or carried on anchoring means comprising a pin which is inserted into an artificial bore in the acetabulum or scapula. Prosthesis components such as these anchoring means are usually cemented into the bone in their respective positions. This is generally achieved by applying cement to the area, cavity or both in which the anchoring means is to be fixed, then positioning the prosthesis component into the cement and holding it in position until the cement sets.

The cementing process in this type of procedure gives rise to a number of problems. Firstly, by its nature cement must set after a given time in its desired location, and this unavoidably puts a time constraint on the procedure between delivery of the cement the time after which the cement sets. For example, many cements are formed by mixing together two constituents to form a composition which sets after a given length of time due, for example, to a chemical reaction such as polymerisation (although cements may be made in other ways and have other constituents such as antibiotic ingredients to prevent infections, Hydroxyl Apatite or heavy elements to aid X-ray imaging for example). Thus, in a conventional procedure, in particular because the

prosthesis or component to be cemented is only positioned after cement has been applied, a surgeon has only the given time to insert the cement and the prosthesis component into position and any mistake or delay may lead to the procedure, in particular correct positioning, not being completed before the cement sets.

Another problem is that the cement should preferably be pressurised in order to force the cement into any cavities and recesses in the region which the cement is intended to fill and to help expel body fluids from that region. However, it can be very difficult to pressurise the cement and, at the same time, position the prosthesis component correctly. Thus, the cement may not be properly pressurised and body fluids may not be properly expelled on pressurisation or may re-enter the area or cavity as the component is being positioned. Such body fluids can weaken the cement fixation and the mounting of the component in the bone.

According to a first aspect of the present invention there is provided apparatus for positioning and cementing a component of or for a prosthesis, the apparatus comprising means for positioning the component in or adjacent a bone cavity, cement delivery means for providing cement under pressure to a cavity space next to the component whilst the component is in its desired position, and a seal carried by the cement delivery means and arranged to confine the cement in such space until it has set.

A further aspect of the invention provides a method of cementing a component of or for a prosthesis into or adjacent a bone cavity, comprising locating the component in a desired position, providing a seal, and providing cement under pressure into a cavity space next to the component and confined by the seal.

Preferably, the provision of cement comprises the provision of cement using a cement delivery means and the provision of a seal comprises locating over a cavity

a seal carried by the cement delivery means and preferably the method also comprises removing the seal when the cement has set.

Thus, a component for a prosthesis such as an anchoring means, or a joint prosthesis component itself, is positioned in or adjacent a bone cavity before the cement is delivered. This enables correct positioning to be achieved without any undue time constraint caused by the cement setting time. Furthermore, cement pressurisation may be carried out with the component in its intended final position, and the pressure can be maintained by the seal until the cement sets. More reliable pressurisation can therefore be achieved and there is less chance of body fluid remaining in the cavity space in which the cement is intended to be located and interfering with fixation of the cement to the surrounding bone. The method and apparatus of the invention are therefore more convenient to use and potentially provide more reliable fixation than the prior art.

The invention is applicable to a wide range of components for placement in the human or animal body, including components for prostheses, e.g. joint replacement prostheses, such as separate anchoring parts or articulating prosthetic parts themselves. The bone cavity into which the component is cemented will vary depending on the component or prosthesis concerned, and may be formed in or comprise a naturally occurring cavity such as a bone canal, recess, indentation or socket, or it may be a cavity which is drilled or reamed by a surgeon especially for location of a prosthesis component. The invention is described below in relation to the anchoring of a cup component in the acetabular socket for an artificial hip prosthesis but, it will be recognised, has wider application.

The invention may find particular utility in minimally invasive joint replacement procedures, such as

that described in WO98/34567. In such minimally invasive procedures it is desirable to insert or locate joint prostheses, or components of such joint prostheses, through an incision distal from the joint, and in the example described in WO98/34567, through a bore in a bone. Thus, access to the location in which the component is to be positioned is restricted, and it is difficult to supply cement and to position the prosthetic component correctly in the time it takes for the cement to set. There is therefore an increased risk of mis-location.

A preferred embodiment of the apparatus therefore comprises a tool provided with carrying means on which the component for the prosthesis is releasably mounted. The component may therefore be positioned by manipulating the tool and held in position thereby until the cement has set, whereupon the component is released from the carrying means. Thus, the component may be guided and manipulated from a position remote from where the component is to be mounted in a body.

Viewed from a still further aspect the invention provides a placement tool for positioning a component of or for a prosthesis, the tool comprising means for detachably mounting the component to a distal end of the tool such that the component is fixed to the tool and can be carried and manipulated thereby, and means for delivering cement for cementing the component on or in a bone within the body whilst the component is still mounted to the tool and positioned thereby.

The tool preferably also comprises a seal as well as cement delivery means so that it provides the triple function of locating the prosthetic component in its desired position, providing a seal adjacent the component, and supplying cement to the cavity space surrounding the component and confined by the seal. The tool may include an elongate, preferably tubular portion, provided at its distal end with the carrying

means for the prosthetic component.

This represents a new departure from the prior art and has significant advantages. The tool may be manipulated manually by a surgeon, or its guidance may be partly or entirely automated. It may be provided with suitable means, such as an endoscope, for providing the surgeon with an image of the site of the prosthesis to assist guidance and location. This may be particularly important in minimally invasive procedures where the surgeon's view of the site is obscured.

Similarly, the tool may be provided with temperature and pressure transducers to either aid automation or to assist a surgeon in noting the pressure being applied on the tool or the temperature of the cement as it sets. This is particularly useful where a surgical procedure is carried out robotically as the temperature and pressure transducers may provide feedback for a computer automation system.

The cement delivery means may comprise a tube, carried by or extending through the tool, through which cement can be provided. Thus, cement may also be provided from a location distal from the position at which the component is to be mounted. Suitable means, such as a piston/cylinder device, may be provided to force cement under pressure, through the tube, and into the bone cavity space around the component and confined by the seal.

The cement may be supplied to the space surrounding the prosthetic component via a suitable aperture in the seal, which aperture would communicate with the cement delivery tube of the tool.

However, in a preferred embodiment which is particularly applicable to generally cup-shaped components of or for prostheses, the cement is preferably supplied via one or more apertures in the component itself. In this way, an uninterrupted and unapertured seal may extend around the prosthetic

component, with the cement being introduced into the space around the component and confined by the seal, through the component.

This represents a new departure from the prior art, and a further aspect of the invention provides a cup-shaped component of or for a prosthesis, which component is intended to be cemented in position, and which includes one or more apertures which are arranged such that cement may be supplied to a space surrounding and/or underlying the component in use.

A further aspect of the invention provides a method of cementing a cup-shaped component of or for a prosthesis, in which cement is provided to a space surrounding and/or underlying the component via one or more apertures in the component.

It is preferred that the tool for positioning a cup-shaped component of or for a prosthesis includes a mating part engageable with the component, with a means for releasably locking the component thereto. The mating part preferably includes one or more cement delivery orifices, which in the preferred embodiments just discussed, communicate with the aperture(s) in the cup component, so that, in use, cement can be supplied, via the aperture(s) to the space beneath and/or surrounding the cup-shaped component whilst it is locked to, and thereby correctly positioned by, the tool. Once the cement has set, the locking means can be released and the positioning tool removed, leaving the component in place.

A preferred form of locking means may comprise retractable locking elements carried by the mating part, which cooperate between the mating part and the cup component.

This aspect of the invention finds particular utility in cementing joint prosthesis, or anchoring means therefor, in sockets of ball and socket joints of the human or animal body, such as the acetabulum or

scapula of the human hip and shoulder joints using, for example, a joint prosthesis such as that described in WO98/34567.

Consequently according to a still further aspect of the present invention there is provided a joint prosthesis for replacing the socket of a ball and socket joint, the joint prosthesis having a generally cup-shaped anchoring means which has one or more apertures through which cement may be provided.

Thus, the anchoring means can be located in, for example, a natural socket, or an artificial bore in a socket, and cement can be then provided to the socket or bore through the aperture(s) in the anchoring means.

The anchoring means may be integral with the joint prosthesis and, if the joint prosthesis comprises, for example, an artificial socket, the aperture(s) may extend through the artificial socket as well as the anchoring means. However, this may mean that a replacement or natural ball rests in the socket over the aperture(s) and this may cause undesirable wear or deterioration of the ball.

It is therefore preferable that where the joint prosthesis is a socket, the aperture(s) are located at a location in the socket that supports the least load from a corresponding ball in use. Thus, the aperture(s) are often located close to the rim of the socket and, as a ball that rests in the socket in use exerts most of its load through the base or centre of the socket, the pressure on the socket over the aperture(s) is reduced and consequently wear and deterioration of the joint prosthesis is reduced.

Alternatively, the anchoring means is detachably mounted to the articulation component of the prosthesis and comprises further means for mounting or receiving such component. For example, the articulation component may be an artificial socket and the receiving means may be a cup for receiving the artificial socket. Thus, the

cement aperture(s) of the anchoring means need not extend into the articulation component since this can be mounted in place after the anchoring means has been cemented in position. The articulation component may be mounted to the anchoring means of the prosthesis by a tapering fit or by corresponding internal and external screw threads on the articulation component and the anchoring means.

The component of or for a prosthesis according to any of the above aspects of the invention may be provided with one or more protrusions which engage the bone and which help maintain the desired position during cement delivery. This is additional to the positioning function achieved by the preferred tool of the invention discussed above.

The seal provided in accordance with the above aspects may take any convenient form suitable for confining the cement in the space surrounding and/or underlying the prosthetic component. In a preferred form, the seal may be of a generally annular or doughnut shape extending around the cement delivery tool such that the seal cooperates in use with the bone surrounding the site for the prosthesis. Cement may then be forced under pressure through the tool into the space adjacent the prosthesis component and confined by the seal, preferably via one or more apertures in the component as discussed.

The seal may be an annular rubber or plastics ring, an umbrella type device or an iris or diaphragm arrangement. However, in a preferred embodiment the seal comprises an inflatable balloon. This has the advantage of providing an improved sealing action against the bone, and may also provide enhanced pressurisation of the cement when inflated. In a preferred apparatus and method, particularly applicable to a minimally invasive technique such as described in WO98/34567, the balloon is deflated and confined in

close proximity to or within the outer periphery of an elongate part of the tool when the tool is initially manipulated to position the prosthetic component in the body. This enables the elongate, preferably tubular, part of the tool provided with the seal to be conveniently inserted through an aperture in a bone, for example, or into or through another confined body space. Once the prosthetic component is correctly positioned, and preferably whilst still attached to the tool, the seal is inflated, for example by a suitable medium, such as saline, via a further conduit in the tool, to provide a seal against the surrounding tissue. Cement may then be forced into the space confined by the seal in a manner as described above.

In one embodiment, the deflated balloon is radially confined whilst the tool is being manipulated in the body. This may be achieved, for example, by retaining means such as an expandable mesh or umbrella device. However, in a preferred embodiment the retaining means comprises a plurality of pins which are initially fixed and extend approximately parallel to the axis of the tool, over the seal. The pins are releasable at their distal ends, and are pivotal in relation to the tool at their proximal ends so that they can be pushed outwardly when the seal is inflated into its sealing condition. Preferably, the retaining means or the pins also function to provide additional support behind the seal when it has been fully inflated.

This, in itself, is a new departure from the prior art and according to a still further aspect of the invention there is therefore provided a delivery device for delivering fluid to a cavity in a bone, the device comprising an elongate supply means having a generally ring or doughnut shaped seal which is carried within the radial dimensions of the supply means as the supply means is inserted, in use, through an orifice into a position for delivering fluid and is expandable outside

the radial dimensions of the supply means to seal the cavity whilst fluid is supplied in use from the supply means to the cavity.

One problem that may occur with inflatable balloon type seals is that, as significant expansion of the balloon may be required to expand the balloon from within the radial confines of a slender tool to a sufficient radius to seal a large cavity in a bone, the material from which the balloon is made may be under significant tension at full radial expansion of the balloon. This, in turn, may make the balloon vulnerable to puncture by, e.g., sharp bone fragments or edges or the tool itself. Similarly, the material may rupture due to inherent weaknesses or expansion beyond the material's inherent elastic limit.

Thus, in a particularly preferred embodiment of the invention the balloon has a relaxed diameter larger than the diameter of the tool and retaining means are provided for retaining the excess balloon material within the diameter of the tool or cement delivery device.

The use of retaining means is, in itself, considered to be a new advantageous departure from the prior art and, according to a further aspect of the present invention, there is provided a tool for sealing a cavity within a human or animal body, the tool comprising an elongate housing and annular seal for sealing the cavity, the seal being confined within the radial dimensions of the elongate housing for insertion of the tool into the human or animal body and expandable beyond the radial dimensions of the elongate housing to seal the cavity.

Preferably, the seal is a balloon. In this case it is preferable that the means for retaining the seal within the radial dimensions of the tool or housing comprises means for extending the balloon along the length of the housing. Thus, in a retracted position,

the balloon extends along the length of the housing, and, in its extended position, the balloon extends along the shorter length of the housing such that it bulges outwardly. This reduces the degree to which the balloon must be inflated to achieve a given radial expansion.

It is preferred that the balloon is made of latex. Likewise, it is also preferred that the balloon has a thickness of between 0.6 and 1 millimetre as this provides sufficient strength and resiliency for sealing cavities in bones.

In addition, the device may preferably, though not essentially, comprise means for detachably mounting, at its distal end, a component, such as a component of a prosthesis, to be secured in a cavity in a bone. This assists in initial positioning of the component, as in earlier aspects of the invention.

In this embodiment, cement can be applied to the cavity in a conventional manner and the tool, can be used to carry the component and position it in the cavity through a small aperture incision or bore, i.e. using minimally invasive surgical techniques. The seal may then be expanded to seal the cavity and/or pressurise cement by which the component is to be fixed into the cavity as appropriate. Likewise, the seal can be retracted to remove the tool through the aperture when the cement has set.

In particular, the component may be releasably attached to the tool as desired. However, in a particularly preferred embodiment the component is attached to the tool by suction. Thus, the tool may be provided with a head arranged to cooperate with the component and provided with a seal for providing an air-tight seal between the head and the component a passage through which the pressure within the space defined by the seal, the head and the component can be reduced to hold the component on the head of the tool. The means for providing a seal may be an 'O'-ring seal, and an

external surface of the head may co-operate with an inside surface of a cap-shaped component to bound the defined space.

The aspect of the invention is again considered to be particularly advantageous in its own right, and to be a departure from the prior art.

Thus, according to a further aspect of the invention there is provided a tool for positioning a component in a human or animal body, the tool comprising an elongate body having a head with a surface arranged to cooperate a surface of the component; a seal for sealing a perimeter of the cooperating surfaces; and a passage for withdrawing air from the space defined by the sealed surfaces so as to releasably hold the component on the head of the tool.

Thus, a component may be attached to the tool by withdrawing air through the passage and, when the component has been positioned correctly in the human or animal body it can be released by releasing the vacuum in the passage. This has the particular advantage in surgical procedures of providing for releasable mounting of a component on a positioning tool without requiring any moving parts within the human or animal body during the procedure. The possibility of malfunction is reduced as there are no moving parts that can become blocked or stuck and prevent release of the component.

According to the present invention there is also provided a cement delivery device for a prosthesis component, comprising cement supply means and a generally ring or doughnut shaped balloon which is carried by a part through which cement for cementing the component in place is supplied in use.

Certain of the above aspects of the invention may also have utility in cementing components, for example anchoring components of joint prostheses, such as elongate pins which are fitted in an elongate artificial bore or natural canal in a bone. For example, femoral

components of hip prostheses are generally located in the medullary canal of a femur. Alternatively, the femoral component may be fitted in an artificial extra-medullary bore, for example as described in WO98/34567. Cement is generally provided from an accessible end of the bore or canal and the anchoring means is then positioned in the bore or canal. However, it is difficult to ensure that cement is provided along the entire length of the bore or canal as it is easy for air or fluid pockets to develop.

The cement delivery means may therefore comprise plural elongate tubes which can extend into a bore or channel in which the component is located and simultaneously provide cement at different radial locations around the component.

This, again, represents a new departure from the prior art, and viewed from a still further aspect of the present invention there is provided an apparatus for delivering cement around a component located in a recess, bore or canal in a bone, the apparatus comprising plural nozzles which can simultaneously provide cement at different circumferential locations around the component.

Thus, cement is provided in a bone recess, bore or canal at more than one radial location and there is less chance of air or fluid pockets developing in the cement.

The nozzles are preferably in the form of elongate tubes which can extend, in use, into a bone cavity such as an elongate bore or canal.

According to a further aspect of the present invention there is provided a method of delivering cement around a component located in a recess, bore or canal of a bone, the method comprising providing cement through one or more elongate tubes and retracting the tube(s) from the recess, bore or canal as the cement is delivered.

Preferably the method further comprises moving the

tube(s) circumferentially around the prosthesis as the cement is delivered. This further enhances the provision of a homogeneous cement mantle and the chance of air or fluid pockets developing in the cement as it is delivered.

In a preferred embodiment of either of the above aspects, the tube or tubes is/are flexible, so that they can more easily be inserted into and withdrawn from an elongate bore or canal in a bone in use.

In a particularly preferred embodiment, two or more ideally four tubes are provided. This is particularly suitable for the risk of high viscosity cement as the tubes can be narrow in cross-section allowing restricted spaces to be assessed whilst providing plural outlet points such that a homogeneous cement mantle can be achieved. In another particularly preferred embodiment, one or more tubes of circumferentially elongate cross-sections are provided. For example, two tubes of horse shoe cross-section may be provided. Such an arrangement is suitable for higher viscosity cements, which require a larger overall cross-section of tubing for successful delivery, whilst still allowing delivery, a circumferentially confined region, such as that around a pin in an elongate bore to be accessed.

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side view of a cement delivery device according to the present invention;

Figure 2 is partial cross sectional view of the cement delivery device of Figure 1 along the line I-I in figure 1;

Figure 3 is view similar to that in Figure 1 of a second cement delivery device according to the invention in use;

Figure 4 is a sectional side view of first example of a component of a joint prosthesis cemented in an

acetabulum;

Figure 5 is a sectional side view of second example of a component of a joint prosthesis cemented in an acetabulum;

Figure 6 is a sectional side view of third example of a component of a joint prosthesis cemented in an acetabulum;

Figure 7 is a sectional side view of fourth example of a component of a joint prosthesis cemented in an acetabulum;

Figure 8 is a sectional side view of a third embodiment of a cement delivery device according to the invention;

Figure 9 is a sectional side view of a fifth example of a component of a joint prosthesis which has been cemented in an acetabulum using the cement delivery device shown in Figure 8;

Figure 10 is a sectional side view of a head of a tool for positioning a component of a joint prosthesis according to the invention with its seal retracted;

Figure 11 is a sectional side view of the head of the tool of Figure 10 with its seal extended;

Figure 12 is a sectional side view of a fourth embodiment of a cement delivery device according to the invention in a femur;

Figures 13a and 13b are views of caps for use with the cement delivery device shown in Figure 12;

Figure 14 is a view of the cement delivery device of Figure 12 in use;

Figure 15 is a sectional side view of a fourth embodiment of a cement delivery device according to the invention in a femur; and

Figure 16 is a view of the delivery device of Figure 15 in use.

Referring to Figure 1, a cement delivery device 1, having a generally elongate construction, is provided. This cement delivery device 1 is particularly suited to

applications in which cement is to be delivered to a location through a restricted orifice, an aperture in body tissue, or a narrow bore in a bone such as described, for example, in WO98/34567 (i.e. minimally invasive surgery). However, the cement delivery device may be used, with or without modification, for other purposes. In particular, use of the device in other applications such as conventional hip replacement procedures may be realised with a construction which is not elongate.

The cement delivery device 1 has main body 2 with a placement head 3 mounted at a distal end of the body 2 such that it can slide in the direction of the longitudinal axis of the body 2 (and cement delivery device 1) toward and away from the body 2. More specifically, the head 3 is mounted on a tube 4 which fits inside a tube 5 in the body 2 having an inner diameter at its distal end the same or slightly larger than the outer diameter of the tube 4. The tubes 4 and 5 form part of a cement delivery passage 16 along the longitudinal central axis of the cement delivery device 1.

Between the head 3 and the body 2, an annular seal 6 extends around the tube 4 of the head 3. When it is required to use the cement delivery device in minimally invasive surgery the seal 6 is collapsable and expandable. This facilitates insertion of the device through a narrow opening or bore and subsequent expansion of the seal to suitable dimensions when the device has been inserted. In this example the seal 6 comprises an annular or doughnut shaped balloon 6 extending around the tube 4. The balloon 6 is inflatable and to allow inflation and deflation the balloon 6 has an opening 7 connected to a passage 8 in the body 2. The passage 8 extends from the balloon to an inlet opening 9 at a proximal end of the body 2 of the cement delivery device 1. The inlet opening 9 is

adapted to receive a connector of a fluid delivery apparatus, such as a syringe, containing saline or some other suitable medium for inflating the balloon 6.

In this example, the head 3 has a shape which tapers away from the body 2 and is arranged to fit with a cup shaped component 10 of a joint prosthesis. However, the component 10 need not be a component of a joint prosthesis, but may equally well be any component for fitting in any cavity or bore (whether natural or artificial) in a bone of a human or animal body, such as an anchoring means for a joint prosthesis or the head of a fracture nail.

The head 3 is provided with one or more retaining pins 11, each slidably disposed in a bore 12 in the head 3, for detachably retaining the component 10 on the head 3. In this example, each bore 12 extends between the cement delivery passage 16 in the head 3 and an outer tapering surface of the head 3. Each retaining pin 11 is slightly longer than the length of the bore 12 in which it is arranged, such that it protrudes either from the tapering surface or into the hollow cavity, and its movement is restricted by a collar in the bore 12 such that it remains in the bore 12. The retaining pins 11 are each arranged to co-operate with an indent 70 in a surface of the component 10 that faces the tapering surface of the head 3. In this example the indent 70 comprises an annular recess running around the surface of the component 10 for engaging all of the retaining pins 11, but smaller individual indents 70 may be provided for each retaining pin 11 if preferred. An actuating tool (not shown) comprising a long shaft with a tapering head or cam surface can be inserted along the cement delivery passage 16 to force the retaining pins 11 outwards, with the component 10 in place on the head, such that the retaining pins 11 protrude from the bores 12 so as to engage the indents of the component 10 and retain the component 10 on the head 3.

At the other, proximal, end of the body 2, there is an opening into the cement delivery passage 16. In Figure 1 a cement injecting apparatus 74 is shown inserted into the passage 16. The cement injecting apparatus 74 comprises an arrangement 75 for carrying and injecting cement and a tube or sleeve 73 which fits in the passage 16.

The distal end of the body 2 (proximal to the head 3) carries retaining means for retaining the balloon 6 within the radial dimensions of the body 2 and for supporting the balloon 6 when it is inflated. In this example, the retaining means comprises a plurality of pins 13 carried by the body 2 and spaced around its circumference. The pins 13 are pivotally connected to the body 2 by pivot means 71 such that they can pivot from a position parallel to the major axis of the body 2 outwardly through an angle A to a position in which they extend partially radially from the body 2, as shown in Figures 1 and 2. To prepare the apparatus for use, the head 3 is moved away from the body 2 and the pins 3 are positioned such that they are parallel to the major axis of the body 2 and retain the balloon 6 under them, within the diameter of the body 2. The head 3 is then moved back toward the body 2 such that the end of each pin 13 distal from its pivotal engagement with the body 2 engages a corresponding recess 14 on a surface of the head 3 facing the body 2. In this position, the pins 13 aid insertion of the cement delivery device 1 through an orifice or bore by confining the balloon 6.

After the device 1 has been manoeuvred into position for delivering cement, the head may be urged away from the body 2. In this example, this is achieved by pushing the sleeve 73 in the passage 16 toward the head 3. As the head 3 moves away from the body 2 the pins 13 disengage from the indent(s) 14 and may be urged outwards by the balloon 6 as it is inflated.

In their deployed condition, as shown in Figures 1

and 2, the pins 13 support the proximal surface of the seal or balloon 6 when it is inflated, as shown in Figure 3. This allows any force exerted along the direction of the major axis of the cement delivery device 1 toward the position of the component 10 or area of cementing to push the seal or balloon 6 as well as the head 3.

Refer now to Figure 3, a cement delivery device 1 similar to that shown in Figures 1 and 2 is shown in position for cementing a component 10 into a socket 18 of an acetabulum 15. This cement delivery device 1 has a head adapted to carry a component which is adapted to be located in pre-drilled holes 76 in a socket or cavity 18, as opposed to on the spike 77 of the component 10 shown in Figure 1. Also, in their deployed condition, the end of each pin 13 proximal to the body 2 rests against a stop 78 which limits the angle A through which the pins can pivot. The pins therefore securely support the inflated balloon 6.

In use, the cement delivery device 1 is inserted through a bore in a bone, such that the head 3 is proximal to a bore, recess or, in this example, a cavity 18 in which a component of a joint prosthesis is to be placed. This is particularly useful when placing the joint prostheses described in International Patent Application No. WO98/34567, which may be put into place through a bore in a femur. The cement delivery device 1 is used to manipulate the component 10 until it is in the correct position. This may be aided by using X-ray imaging to show the position of the component next to the bone. The manipulation may be carried out by a robotic or other computer-aided surgical technique. Marks may be provided or placed on the body 2 of the cement delivery device 1 to help to show the position of the component 10 either visually or in X-ray imaging. For example, the length of the body 2 may be marked with indications along its length which may, for example, protrude from the diameter of the body 2 to show up in

X-ray imaging. Similarly, the devices may be fitted with temperature and/or pressure transducers to provide feedback to an automated system. Still further, the cement delivery device 1 may have a cooling system, for example comprising tubes for carrying coolant around the body 2, to regulate the temperature of the cement as it is injected into a cavity or bore and sets.

Once the component 10 has been correctly located in the bone 15, such as an acetabulum 15, as shown in Figure 3, the balloon 6 is inflated by passing a suitable medium, such as saline, through inlet opening 9 and along the passage 8. The balloon 6 expands to form a seal with tissue in the socket of the acetabulum 15. The balloon 6 may seal the cavity by taking any suitable shape, but the seal shown in this example is particularly adapted for sealing a socket or cup shaped cavity (such as the acetabulum 15 shown in Figure 3) as it presses radially outward against a ring of tissue or bone rather than resting on the rim of bone surrounding the socket. In this position, the pins 13 support the balloon 6 such that it does not pop out of the socket, and such that it exerts some pressure on the cavity 17 formed between the balloon 6 and the socket 18. A force toward the cavity 18 is maintained on the device by a robot arm, automated clamp type device or manually by a surgeon, to keep the seal in place and hold the component still.

With the component 10 correctly positioned and the seal properly positioned, or balloon 6 properly inflated, to form a suitable seal, cement is injected using the cement injecting apparatus 74 along the passage 16 or, more specifically, through the sleeve 73 in the passage 16. The cement passes along the sleeve 73 and through one or more openings in the component 10 into the cavity 17 between the balloon and the acetabular socket 18. The cement can be provided at a pressure higher than that of fluids within the body such

that any fluid in the cavity 17 is driven out of the cavity 17 and the cavity 17 is filled with cement.

The cement delivery device 1 and balloon 6 remain in position until the cement has set. The fluid in the balloon 6 is then removed through the inlet opening 9 to deflate the balloon 6 and allow the pins 13 to collapse inwardly. The cement delivery device 1 can then be removed from the bore or orifice through which it was inserted.

Various components may be cemented using the cement delivery device described above. Referring to Figure 4, in one embodiment, a socket component 19 of a joint prosthesis is cemented in place using the cement delivery device 1. This component 19 has two apertures 20 through which cement may be passed to cement the component 19 in place. Additionally, in the embodiment shown the acetabular socket 17 has been prepared by drilling a number of holes 72 in its surface to aid location of the cement and strengthen the bond between the cement and the bone.

The apertures 20 through which cement is injected are located close to the rim of the socket 21 of the component 19. Thus, when a ball is placed in the socket 21 to complete the joint prosthesis, the major forces exerted on the socket are not exerted in the area of the apertures 20. This reduces any erosion or wear that may be caused by the ball rotating over cement exposed in the apertures 20.

Referring to Figure 5, a third embodiment of component 10 is shown. This two part component 22 comprises an anchoring part or anchoring means 24 and an articulation part 23. The anchoring part 24 is cemented in place in a similar manner to the components 10 and 19 of the above described embodiments, i.e. it is put in position using a cement delivery device 1, a seal is provided and cement is injected. However, the anchoring part 24 does not have a socket 21, but instead has a

tape recess 25 for receiving a portion 26 of the articulation part 23. Thus, cement can be inserted through apertures (not shown) in the anchoring part 24, and the articulation part 23 can be located in the anchoring part 24 after the anchoring part 24 has been cemented in place. In this example, the portion 26 of the articulation part 23 fits in the recess 25 of the anchoring part 24 by a friction fit. The articulation part 23 and the component 22 generally, provide a smooth socket 27 which has no apertures in its surface. This further reduces wear of a ball and socket joint.

Referring to Figure 6, in a fourth embodiment a two-part component 22 of a joint prosthesis is again provided. However, in this example an anchoring part 28 is cemented in place and articulation part 29 component having a socket 30 is joined to the anchoring part 28 by means of a screw thread, rather than the friction fit of tapering surfaces.

Referring to Figure 7, a fifth embodiment of a component of a joint prosthesis comprises a pin 31 which may be inserted into an artificial bore 32 in an acetabulum 15. In this example, the pin 31 comprises two parts, a first outer sleeve 33 having orifices 34 through which cement can be inserted, and a second inner sleeve 35 which fits inside the outer sleeve 33 to provide a stable support. The outer sleeve 33 is fitted in a similar manner to the anchoring parts of the above described embodiment and the inner sleeve 35 in position later.

Referring to Figures 8 and 9, a sixth embodiment of a component for a joint prosthesis comprises a cup-shaped component 40. It can be appreciated that a component 40 having dimensions similar to that shown in the Figure cannot be inserted through a narrow bore or orifice, and it is intended that this is inserted in an acetabulum using a conventional joint replacement technique. However, a cement delivery device 1 in

accordance with the invention may still be utilised, although it is preferred that the cement delivery device then comprises a head 41 (as shown in Figure 9) having a larger diameter than the head 3 of previous embodiments.

The head 41 has an annular seal 43 which fits over the bone or tissue surrounding the socket 17 of the acetabulum 15 to provide a seal which is supported by pressure exerted through the cement delivery device 1 towards the socket 17, rather than radially outwards around the inside of the rim of the socket 17 as in the previous embodiments described above. The annular seal 43 need not be inflatable, and may comprise a sealed annular 'O'-ring.

The head 41 has two or more passages 42 for delivering cement through apertures 78 at the periphery of the component 40. Thus cement is injected around the periphery of the socket 17 and a more homogeneous cement mantle may be provided. A further annular seal 78 is provided inward of the passages 42 to prevent cement from entering the artificial socket 79. Pins 80 on the head 41 engage recesses 81 to hold the component 40 during positioning and cement delivery.

Referring to Figures 10 and 11, a tool 100 for positioning a component of a joint prosthesis, which can be used in a slightly more conventional method of fixing components to bones, has a number of features in common with the cement delivery devices described above.

The tool 100 comprises an elongate housing 101 which, in this example, is suitable for positioning a component of a prosthesis by inserting it through a bore in a bone such as described in WO98/34567. At the distal end of the housing 101, a head 102 is provided for carrying the component. The head comprises a domed or conical surface adapted to mate with a surface of the component (in this case a socket of a ball and socket joint to be mounted in an acetabulum).

Passing through the central axis of the dome or

cone of the head is a passage 103 connected to a main passage 104 passing along the length of the housing 101 of the tool 100. Outwardly of the opening of the passage 103 in the head 102 is an 'O'-ring seal 105 adapted to form a seal with the component when it is mounted on the head 103. In this example, the 'O'-ring seal is an annulus around the base of the domed or conical surface of the head 103.

Rearwardly or behind the head 103, the tool 100 carries a balloon 106. The balloon 106 comprises a tube of suitably pliable and elastic material such as rubber or latex. Typically, a thickness of 0.6 millimetres to 1 millimetre is suitable.

The balloon 106 extends from a fixed collar 107 just behind the head 102 to a movable collar 108 provided within the housing 101. One end of the balloon is sandwiched between a base 109 and retaining portion 110 of the fixed collar 107 and two 'O'-rings seals are provided between the balloon and the retaining portion 110 to provide a water-tight seal around the entire circumference of that end of the balloon.

The movable collar 108 similarly comprises a base 112 and a retaining cover 113, this time sandwiching the other end of the balloon 106. Again, 'O'-ring seals are provided between the balloon 106 and the retaining cover 113 to ensure a water-tight seal around the entire circumference of that end of the balloon 106. The base 112 and retaining cover 113 of the movable collar 108 are fixed to an accuator, which in this example comprises a tube 115 disposed within the housing 101. In this example, the base 112 and retaining cover 113 of the movable collar 108 are attached to the tube 115 by sandwiching the tube 115. The whole assembly of the tube 115, collar 108 and balloon 106 is slidable within the housing 101, although the distal end of the balloon, behind the head 102 is fixed. Thus, the balloon 106 extends between two cars or collars 107, 108, one of

which is movable to decrease the length of the balloon 106 and accordingly increase its diameter.

In this example, around 40 to 50 millimetres of balloon material extends between the collar just behind the head 102 to the movable collars 107, 108. However, the housing extends forward of the movable collar 108 in its retracted position shown in Figure 10, and only a small gap, in this example 20 millimetres, is provided between the head 102 and the housing 101 at which the balloon is exposed.

A fluid passage 105 extends along the length of the housing 101 into the space defined inwardly of the balloon 106. Fluid, such as saline, can be injected into the space to inflate the balloon 106. The movable collar 108 slides forward on inflation to increase the diameter of the balloon. Thus, the balloon 106 need not be as elastic as the balloon as the embodiments described above, as the balloon 106 is not required to inflate to the same extent.

In use, cement is first applied to the area to which a component for a prosthesis is to be attached. The tool 100 is prepared by placing the component (such as that illustrated in Figure 4 although without the apertures 20 through which cement is injected) on the head 102 of the tool 100. A seal is formed between the rim of the component and the 'O'-ring 105 and air is withdrawn through the passages 103 and 104 such that the component is held on the head 102 by vacuum.

The tool 100, carrying the component is then inserted by the incision or bore through which access is gained to the area or cavity in which the component is to be fixed, such that the component is brought into a position close to the position in which it is to be fixed. The balloon 106 is in the retracted position shown in Figure 10 during insertion such that the balloon is protected and the tool 100 can be easily inserted through the incision or bore.

Once the tool 100 and component are in position close to the intended position in which the component is to be fixed, the collar 108 is moved towards the distal end of the tool 100 and saline is injected into the space defined by the balloon 106 through the passage 115 to inflate the balloon 106. The balloon 106 is thus inflated as shown in Figure 11 without the material from which the balloon is made being stretched to a large extent. This reduces the possibility of the balloon 106 being punctured or ruptured due to contact with bone or body tissues, as the balloon 106 does not stretch to a large extent.

The tool 100 is then pushed forward such that the component is brought forward into the final position in which the component is to be fixed and the balloon 106 seals the cavity or area in which cement has been provided and pressurises the cement. This ensures that any bodily fluids are expelled from the area of the cement and that a homogenous cement mantel is produced.

When the cement has set, the vacuum or reduced pressure in the passages 103 and 104 is released such that the component is no longer held on the head 102 and the tool 100 is released. Likewise, saline is withdrawn from the balloon 106 of the movable collar 108 is moved away from the head such that the balloon 106 is retracted. The tool 100 may then be withdrawn through the bore or incision through which it was inserted.

Referring to Figures 12, 13a and 13b, in a further embodiment the cement delivery device has a plurality of tubes 50 which extend from the end of the cement delivery device into a cavity in which cement is to be injected. In the example illustrated in Figures 12, 13a and 13b, a component 52 is cemented in an extra-medullary bore 54 in a femur 51. The component 52 has a seal 53 at its medial, wider end, which seals one end of the bore 54. A cap 55 or 57, as shown in Figures 13a or 13b, is fitted over the other end of the bore 54. This

engages the distal end of the component 52 to hold it along the central axis B of the bore 54. In this example, the cap 55 or 57 also seals the end of the bore over which it fits. The cap 55 has a plurality of apertures 56 (shown in Figures 13a and 13b) through which the cement delivery tubes 50 can be inserted and, in use, the delivery tubes 50 are inserted through the cap 55 or 57 as far as the seal 53.

As shown in Figure 14, as cement is injected through the tubes 50 into the cavity 54, the tubes 50 are gradually withdrawn from the cavity. This results in a particularly homogeneous cement mantle which is stronger than those of the prior art.

Alternatively, the apertures 56 may formed as slots which extend circumferentially around the cap 55 or 57, or the cap 55 or 57 may be arranged to rotate. This enables the tubes 50 to be rotated circumferentially around the pin 52 as they are withdrawn (i.e. along generally helical paths) which also aids the provision of a homogenous cement mantle.

Referring now to Figure 15, the cement delivery device of the above embodiment can be adapted for use with a femoral component 63 which extends along the medullary canal of a femur 51. In this example, the medullary canal 60 is plugged at its lower end with a seal 61, and the femoral component 63 is inserted in the bore 60. Referring to Figure 16, cement is delivered to the bore 62 in a way similar to that of the above embodiment, by withdrawing the tube 64 from the bore 62 as cement is injected. To aid provision of a homogeneous cement mantle, the tubes may be rotated around the circumference of the bore as they are withdrawn, although this is only possible where the shape of the prosthesis 63 or other component being cemented in position allows.

In the embodiments shown in Figures 12 and 13a four flexible tubes 50, which are circular in cross-section,

are provided. Such an arrangement is suitable for the application of low viscosity cement. In an alternative arrangement, larger diameter tubes 50 may be used for higher viscosity cements, which generally have quicker setting times and are generally advantageous as they can reduce the length of surgical procedures. In particular, two tubes 50 may be used each having a horse shoe cross-section. Such an arrangement uses a cap 57, as shown in Figure 13b, having two apertures comprising diametrically opposed horse shoe shaped slots. This arrangement is useful for the application of higher viscosity cement around a component, such as that shown in Figure 12 in a circumferentially confined space as it maximises the cross-sectional area of the cement delivery tubes for a given circumferential space.

It will be understood that the above described embodiments may be adapted or varied within the scope of the claimed invention. For example, the device 1 may not have means for placing a component and may instead be used fill joints or, if preferable, to place cement in a cavity or bore in a bone before a component is positioned, as the device still has the advantage of being able to cleanly and reliably deliver cement to a cavity or bore through a small aperture or bore. Likewise, the various corresponding features of each of the various embodiments are broadly interchangeable with one another.